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## In The United States Patent and Trademark Office

In re Application of:

Group Art Unit: 1641

Inventors: Cleland et al.

Examiner: Ryan, V.

Application No: 08/846,933

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Filed: April 30, 1997

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For: METHODS AND COMPOSITIONS FOR  
MICROENCAPSULATION OF  
ANTIGENS FOR USE AS VACCINES

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## INFORMATION DISCLOSURE STATEMENT

Assistant Commissioner for Patents  
Washington, D.C. 20231

Sir:

In accordance with 37 C.F.R. § 1.56, the references listed on the attached Form PTO-1449 are being brought to the attention of the Examiner for consideration in connection with the examination of the above-identified patent application.

1. United States Patent No. 3,565,559 issued 02/23/71 to Sato et al.;
2. United States Patent No. 3,737,337 issued 06/05/73 to Schnoring et al.;
3. United States Patent No. 4,293,539 issued 10/06/91 to Ludwig et al.;
4. United States Patent No. 4,389,330 issued 06/21/83 to Tice et al.;
5. United States Patent No. 4,524,067 issued 06/18/85 to Archi et al.;
6. United States Patent No. 4,568,559 issued 02/04/86 to Nuwayser et al.;
7. United States Patent No. 4,637,905 issued 01/20/87 to Gardner;
8. United States Patent No. 4,652,441 issued 03/24/87 to Okada et al.;
9. United States Patent No. 4,675,189 issued 06/23/87 to Kent et al.;
10. United States Patent No. 4,719,246 issued 01/12/88 to Murdoch et al.;

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Docket No.: 14918-707 CPA4

11. United States Patent No. 4,728,721 issued 03/01/88 to Yamamoto et al.;  
12. United States Patent No. 4,767,628 issued 08/30/88 to Hutchinson et al.;  
13. United States Patent No. 4,849,228 issued 07/18/89 to Yamamoto et al.;  
14. United States Patent No. 4,897,268 issued 01/30/90 to Tice et al.;  
15. United States Patent No. 4,902,515 issued 02/20/90 to Loomis et al.;  
16. United States Patent No. 4,917,893 issued 04/17/90 to Okada et al.;  
17. United States Patent No. 4,919,929 issued 04/24/90 to Beck et al.;  
18. United States Patent No. 4,954,298 issued 09/04/90 to Yamamoto et al.;  
19. United States Patent No. 4,962,091 issued 10/09/90 to Eppstein et al.;  
20. United States Patent No. 4,990,336 issued 02/05/91 to Silvestri et al.;  
21. United States Patent No. 5,008,116 issued 04/16/91 to Cahn;  
22. United States Patent No. 5,015,476 issued 05/14/91 to Cochrum et al.;  
23. United States Patent No. 5,057,540 issued 10/15/91 to Kensil et al.;  
24. United States Patent No. 5,068,112 issued 11/26/91 to Samejima, et al.;  
25. United States Patent No. 5,075,109 issued 12/24/91 to Tice et al.;  
26. United States Patent No. 5,100,669 issued 03/31/92 to Hyon et al;  
27. United States Patent No. 5,126,147 issued 06/30/92 to Silvestri et al.;  
28. United States Patent No. 5,198,533 issued 03/30/93 to Schally et al.;  
29. United States Patent No. 5,242,686 issued 09/07/93 to Chu et al.;  
30. United States Patent No. 5,348,867 issued 09/20/94 to Georgiou et al;  
31. United States Patent No. 5,624,612 issued 04/29/97 to Sewall et al.;  
32. United States Patent No. 5,643,605 issued 07/01/97 to Cleland et al.;  
33. United States Patent No. 5,667,808 issued 09/16/97 to Johnson et al.;  
34. Australian Patent No. 7,992,987 issued 04/01/88;  
35. European Publication No. 266,119 A2 published 05/04/88;  
36. European Publication No. 279,688 A2 published 08/24/88;  
37. European Publication No. 333,523 A2 published 09/20/89;  
38. European Publication No. 399,843 A2 published 11/28/90;  
39. European Publication No. 442,671 A2 published 08/21/91;  
40. PCT Publication No. WO 90/03984 published 04/19/90;

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41. PCT Publication No. WO 90/09166 published 08/23/90;
42. PCT Publication No. WO 91/12882 published 09/05/91;
43. PCT Publication No. WO 91/15238 published 10/17/91;
44. PCT Publication No. WO 93/07861 published 04/29/93;
45. Swedish Application No. 8,803,621 issued 04/13/90 (abstract only);
46. Arthur et al., "Challenge of chimpanzees (*Pan troglodytes*) immunized with human immunodeficiency virus envelope glycoprotein gp120" Journal of Virology 63 (12) : 5046-5053 (1989);
47. Berman et al., "Human Immunodeficiency virus type 1 challenge of chimpanzees immunized with recombinant envelope glycoprotein gp120" Proc. Natl. Acad. Sci. USA 85(14) : 5200-5204 (July 1988);
48. Chang et al., "Biodegradable Semipermeable Microcapsules Containing Enzymes, Hormone, Vaccines, and Other Biologicals" J. Bioengineering 1:25-32 (1976);
49. Chen Science 262:980-981 (1993);
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51. Cowsar et al., "Poly (lactide-co-glycolide) Microcapsules for Controlled Release of Steroids" Methods in Enzymology 112 (Drug and Enzyme Targ) 101-116 (1985);
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54. Esparza et al., "Parameters Affecting the Immunogenicity of Microencapsulated Tetanus Toxoid" Vaccine 10(10): 714-720 (1992);
55. Glaser, V., "Solving the HIV Vaccine Puzzle: Questions Still Outnumber the Answers" Genetic Engineering News pps. 15-30 (November 1, 1993);
56. Hora, et al., "Release of Human Serum Albumin from Poly(lactide-co-glycolide) Microspheres" Pharmaceutical Research, 7(11):1190-1194 (1990);
57. Hu et al., "Effect of immunization with a vaccinia-HIV env recombinant on HIV infection of chimpanzees" Nature 328 (6132):721-723 (August 1987);
58. Kensil et al., "Development of a genetically engineered vaccine against feline leukemia virus infection" J. Amer. Veterinary Med. Assoc. 199(10):1423-1427 (1991);
59. Kohn et al., "Single Step Immunization Using a Controlled Release, Biodegradable Polymer With Sustained Adjuvant Activity" J. Immun. Methods 95:31-38 (1986);

60. Maulding, "Prolonged Delivery of Peptides by Microcapsules" J. of Controlled Release 6:167-176 (1987);
61. Nellore et al., "Evaluation of Biodegradable Microspheres as Vaccine Adjuvant for Hepatitis B Surface Antigen" Journal of Parenteral Science & Technology, Vol. 46, No. 5: 176-180 (September-October 1992);
62. Nunberg et al., "Adjuvant Formulations to Increase the Virus-neutralizing Antibody Response to HIV-1 rgp120 Subunit Vaccine" Vaccines (Annu. Meet.), Norrby et al., 11th edition, N.Y.:Cold Spring Harbor Lab Vol. 94:23-27 (Mod. Approaches New 1994);
63. O'Hagan et al., "Biodegradable Microparticles as Controlled Release Antigen Delivery System" Immunology 73(2):239-242 (1991);
64. Payne et al., "Water Soluble Phosphazene Polymers for Parenteral and Mucosal Vaccine Delivery" Vaccine Design: The Subunit Adjuvant Approach, Powell et al., New York, NY: Plenum Press Vol. 6:473-493 (1995);
65. Preis, I. and Langer, R., "A Single-step Immunization by Sustained Antigen Release" J. Immun. Methods 28:193-197 (1979).
66. Putney, S., "How Antibodies Block HIV Infection: Paths to an AIDS Vaccine" TIBS 17:191-196 (1992);
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69. Watts et al., "Microencapsulation Using Emulsification/Solvent Evaporation: An Overview of Techniques and Applications" Critical Reviews in therapeutic Drug Carrier Systems, Vol. 7, Issue 3: 235-259 (1990);
70. White et al., "A purified Saponin Acts as an Adjuvant for a T-independent Antigen" Immunobiology of Proteins and Peptides VI, M.Z. Atassi, New York:Plenum Press pps. 207-210 (1991);
71. Wu et al., "Saponin Adjuvant Enhancement of Antigen-Specific Immune Responses To An Experimental HIV-1 Vaccine" J. of Immuno. 148(5):1519-1525 (1992);

#### I. Timing of the Information Disclosure Statement:

This Information Disclosure Statement:

[ ] Accompanies the new patent application submitted herewith. 37 CFR  
§ 1.97(a).

Is filed within three months after the filing date of the application or within three months after the date of entry of the national stage of a PCT application as set forth in 37 CFR § 1.491.

As far as is known to the undersigned, is filed before the mailing date of a first Office Action on the merits. In the event, however, that an Office Action has crossed in the mail with this Information Disclosure Statement, the Commissioner is hereby authorized to charge Deposit Account No. 13-0257 for any fees required pursuant to 37 CFR §§ 1.17(p) or 1.17(i)(1).

Is filed after the first Office Action and more than three months after the application's filing date or PCT national stage date of entry filing but, as far as is known to the undersigned, prior to the mailing date of either a final rejection or a notice of allowance and is accompanied by either the fee (\$240) set forth in 37 CFR § 1.17(p) or a certification as specified in 37 CFR § 1.97(e), as checked below.

Is filed after the mailing date of either a final rejection or a notice of allowance, whichever occurred first, and is accompanied by the fee (\$130) set forth in 37 CFR § 1.17(i)(1) and a certification as specified in 37 CFR § 1.97(e), as checked below. This document is to be considered as a petition requesting consideration of the Information Disclosure statement.

*If either of the two immediately preceding paragraphs above referring to a certification are checked, the following "certification" under 37 CFR § 1.97(e) may need to be completed.* The undersigned certifies that:

Each item of information contained in the Information Disclosure Statement was cited in a communication mailed from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement.

No item of information contained in this Information Disclosure Statement was cited in a communication mailed from a foreign patent office in a counterpart foreign application or, to the knowledge of the undersigned after making reasonable inquiry, was known to any individual designated in 37 CFR § 1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

## II. Copies of the Cited Items:

Copies of all of the items listed on the attached Form PTO-1449 are enclosed.

Copies of only the following items listed on the attached Form PTO-1449 are enclosed:

Copies of those items which are marked with an asterisk (\*) in the attached Form PTO-1449 are not supplied because they were previously cited by or submitted to the Office in prior Application No. 08/143,555, filed October 25, 1993 or in prior application No.

08 447,291, filed May 22, 1995, both of which are relied upon in this application for an earlier filing date under 35 U.S.C. § 120. See 37 C.F.R. § 1.98(d).

Copies of those items which are marked with a double asterisk (\*\*) in the attached Form PTO-1449 are not supplied because they are U.S. patent application(s) and no copy of a U.S. patent application needs to be provided pursuant to 37 C.F.R. § 1.98(a)(2)(iii).

### **III. Concise Explanation of Relevance:**

A concise explanation of relevance of the items listed on Form PTO-1449 is not given.

A concise explanation of relevance of [some of] the items listed on Form PTO-1449 is in the form of an English language copy of a Search Report from a foreign patent office, issued in a counterpart application, which refers to the relevant portions of the references [copy attached].

A concise explanation of relevance of the items listed on form PTO-1449 is given for only non-English language listed item(s). Specifically, the following foreign-language documents are being brought to the attention of the Examiner along with a concise explanation of the relevance of each document, as it is presently understood by the individual designated in 37 C.F.R. § 1.56(c) most knowledgeable about the content of the information in each document:

### **IV. Conclusion:**

Citation of the above documents shall not be construed as:

1. an admission that the documents are necessarily prior art with respect to the instant invention;
2. a representation that a search has been made, other than as described above; or
3. an admission that the information cited herein is, or is considered to be, material to patentability as defined in § 1.56(b).

It is respectfully requested that the Examiner indicate consideration of the cited references by returning a copy of the attached form PTO 1449 with initials or other appropriate marks.

The Commissioner is hereby authorized to charge Deposit Account No. 13-0257 (for 14918-707 CPA4) for any additional fees required in connection with the filing of this Information Disclosure Statement.

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Dated: August 5, 1999

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